



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bernard Moss et al.

Art Unit : 1645

Serial No.: 10/646,628

Examiner: R. Zeman

Filed

: August 22, 2003

Title

: MVA EXPRESSING MODIFIED HIV ENVELOPE, GAG, AND POL GENES

## MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request.

This statement is being filed before receipt of a first office action. Please apply any charges or credits to Deposit Account No. 06-1050, referring to attorney docket 12804-027001.

Respectfully submitted,

Date:

27 July 2005

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Anita L. Meiklejohn, Ph.D. Reg. No. 35,283

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Substitute form PTO-1449

(Modified)

AUG 1 2006 ormation Disclosure Statement

by Applicant

(Use several sheets if necessary)

Attorney's Docket No. 12804-027001

Application No. 10/646,628

Applicant

Bernard Moss et al.

Filing Date

Group Art Unit

August 22, 2003 1645

			U.S. Pate	ent Documents		<u> </u>	
Exami ner Initial	_Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,169,763	12/1992	Kieny et al.			
	AB	5,256,767	10/1993	Salk and Carlo			
	AC	5,445,953	08/1995	Dorner et al.			
	AD	5,494,807	02/1996	Paoletti et al			
	AE	5,589,466	12/1996	Felgner et al.			
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	AG	5,614,404	03/1997	Mazzara et al.			
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	AI	5,736,368	04/1998	Mazzara et al.	435	320.1	
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	AK	5,747,324	05/1998	Mazzara et al.			
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	AM	5,756,103	05/1998	Paoletti et al.	424	160.1	
	AN	5,766,599	06/1998	Paoletti et al.	435	5	
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	AS	5,863,542	01/1999	Paoletti et al.			
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	AY	6,077,662	6/2000	Compans et al.	435	5	
	AZ	6,080,408	06/2000	Rovinski et al.			

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449  (Modified)  U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 12804-027001	Application No. 10/646,628	
by Ap	closure Statement	Applicant Bernard Moss et al.		
(Use several sheets if necessary) (37 CFR \$1.98(b))		Filing Date August 22, 2003	Group Art Unit	

			U.S. Pate	ent Documents			
Exami ner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AAA	6,086,891	07/2000	Hurwitz and Coleclough			
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	AGG	6,171,596	01/2001	Earl et al.			
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	AII	6,204,250	03/2001	Bot and Bona			
	AJJ	6,214,804	04/2001	Felgner et al.			
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	Foreign Patent Documents or Published Foreign Patent Applications							
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	APP	WO 97/27311	7/1997	WIPO				
	AQQ	WO 98/56919	12/1998	PCT International				
	ARR	WO 00/00216	01/2000	PCT International				
	ASS	WO 01/02607	01/2001	PCT International				
,	ATT	WO 01/52886	07/2001	PCT International				
	AUU	WO 01/82962	11/2001	PCT International				·¥ii
	AVV	WO 02/072754	9/2002	WIPO				

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	Foreig	n Patent Doo	uments or P	ublished Foreign	Patent A	Application	าร	
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ner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Yes	No
	AWW	WO 03/004657	1/2003	WIPO				

	Other D	ocuments (include Author, Title, Date, and Place of Publication)
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ner	D:- ID	
Initial	Desig. ID	Document Document
	AXX	Amara et al., "Different Patterns of Immune Responses but Similar Control of a Simian-Human Immunodeficiency Virus 89.6P Mucosal Challenge by Modified Vaccinia Virus Ankara (MVA) and DNA/MVA Vaccines," J. Virology 76:7625-7631 (2002)
	AYY	Andre et al., "Increased immune response elicited by DNA vaccination with a synthetic gp120 sequence with optimized codon usage," J. Virol., 72: 1497-1503, 1998.
	AZZ	Antoine et al., "The Complete Genomic Sequence of the Modified Vaccinia Ankara Strain: Comparison with Other Orthopoxviruses", Virology, 244: 365-96, 1998.
	AAAA	Asakura et al., "Induction of HIV-1 specific mucosal immune responses by DNA vaccination," Scand. J. Immunol., 46: 326-330, 1997.
	ABBB	Bachmann and Zinkernagel, "Neutralizing antiviral B cell responses," in Ann. Rev. Immunol., 15: 235-270, 1997.
	ACCC	Barouch et al., "Reduction of Simian-human immunodeficiency virus 89.6P viremia in rhesus monkeys by recombinant modified vaccinia virus Ankara vaccination," J. Virol., 75: 5151-5158, 2001.
	ADDD	Barouch et al., "Augmentation of immune responses to HIV-1 and simian immunodeficiency virus DNA caccines by IL-2/IG plasmid administration in rhesus monkeys", Proc. Natl. Acad. Sci. U.S.A., 97:4192-7, April 11, 2000.
	AEEE	Barry et al., "Protection against mycoplasma infection using expression-library immunization," Nature, 377: 632-635, 1995.
:	AFFF	Berger, "HIV Entry and Tropism: the chemokine receptor connection," AIDS, 11(Suppl. A): S3-16, 1997.
	AGGG	Benson et al., J. Virol., "Recombinant vaccine-induced protection against the highly pathogenic simian immunodeficiency virus SIV(mac251): dependence on route of challenge exposure," 72: 4170-4182, 1998.
	АННН	Blanchard <i>et al.</i> , "Modified vaccinia virus Ankara undergoes limited replication in human cells and lacks several immunomodulatory proteins: implications for use as a human vaccine," J. Gen. Virol., 79: 1159-1167, 1998.
	AIII	Bohm et al., "DNA vector constructs that prime hepatitis B surface antigen-specific cytotoxic T lymphocyte and antibody responses in mice after intramuscular injection," J. Immuno. Methods, 193: 29-40, 1996.
	AJJJ	Bohm et al., "Routes of plasmid DNA vaccination that prime murine humoral and cellular immune responses," Vaccine, 16: 949-54, 1998.
	AKKK	Bolivar et al., "Construction and Characterization of New Cloning Vehicles: (II. A Multipurpose Cloning System)," Gene, 2: 95-113, 1977.

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	Other D	ocuments (include Author, Title, Date, and Place of Publication)
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Initial	Desig. ID	Document
	ALLL	Boyer <i>et al.</i> , "Protection of chimpanzees from high-dose heterologous HIV-1 challenge by DNA vaccination," Nature Med., 3: 526-532, 1997.
	AMMM	Boyle <i>et al.</i> , "Influence of cellular location of expressed antigen on the efficacy of DNA vaccination: cytotoxic T lymphocyte and antibody responses are suboptimal when antigen is
	_	cytoplasmic after intramuscular DNA immunization," Int. Immunol., 9: 1897-1906, 1997.
	ANNN	Boyle et al., "Enhanced responses to a DNA vaccine encoding a fusion antigen that is directed to sites of immune induction," Nature, 392: 408-411, 1998.
	A000	Burton and Montefiori, "The antibody response in HIV-1 infection," AIDS, 11(Suppl A):S87-98, 1997.
	APPP	Burton et al., "Why do we not have an HIV vaccine and how can we make one?" Nature Med. 4:495-498, 1998.
	AQQQ	Calarota <i>et al.</i> , "Cellular cytotoxic response induced by DNA vaccination in HIV-1-infected patients," Lancet, 351: 1320-1325, 1998.
	ARRR	Cardoso <i>et al.</i> , "Immunization with Plasmid DNA Encoding for the Measles Virus Hemagglutinin and Nucleoprotein Leads to Humoral and Cell-Mediated Immunity," Virology, 225: 293-299, 1998.
	ASSS	Carroll and Moss, "Host Range and Cytopathogenicity of the Highly Attenuated MVA Strain of Vaccina Virus: Propagation and Generation of Recombinant Viruses in a Nonhuman Mammalian Cell Line", Virology, 238:198-211, 1997.
	ATTT	Chapman <i>et al.</i> , "Effect of intron A from human cytomegalovirus (Towne) immediate-early gene on heterologous expression in mammalian cells," Nucl. Acids Res., 19: 3979-3986, 1991.
	AUUU	Chen et al., "Protective Immunity Induced by Oral Immunization with a Rotavirus DNA Vaccine Encapsulated in Microparticles," J. Virol., 72: 5757-5761, 1998.
	AVVV	Chun et al., "Early establishment of a pool of latently infected, resting CD4+ T cells during primary HIV-1 infection," Proc. Natl. Acad. Sci. USA, 95: 8869-8873, 1998.
	AWWW	Collman et al., "An Infection Molecular Clone of an Unusual Microphage-Tropic and Highly Cytopathic Strain of Human Immunodeficiency Virus Type 1," J. Virol., 66: 7517-7521, 1992.
·	AXXX	Condon et al., "DNA-based immunization by in vivo transfection of dendritic cells," Nat Med., 2:1122-1128, 1996.
	AYYY	Corr et al., "Gene Vaccination with Naked Plasmid DNA: Mechanism of CTL Priming," J. Exp. Med., 184: 1555-1560, 1996.
	AZZZ	Dempsey et al., C3d of Complement as a Molecular Adjuvant: Bridging Innate and Acquired Immunity," Science, 271: 348-350, 1996.
	AAAAA	Durbin et al., "Comparison of the immunogenicity and efficacy of a replication-defective vaccinia virus expressing antigens of human parainfluenza virus type 3 (HPIV3) with those of a live attenuated HPIV3 vaccine candidate in rhesus monkeys passively immunized with PIV3 antibodies," J. Infect. Dis., 179: 1345-1351, 1999.
	ABBBB	Durbin et al., "The immunogenicity and efficacy of intranasally or parenterally administered replication-deficient vaccinia-parainfluenza virus type 3 recombinants in rhesus monkeys", Vaccine, 16: 1324-30, 1998.
	ACCCC	Endo et al., "Short- and Long-term Clinical Outcomes in Rhesus Monkeys Inoculated with a Highly Pathogenic Chimeric Simian/Human Immunodeficiency Virus", J. Virol., 74:6935-45, 2000.

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Information Disclosure Statement by Applicant		Applicant Bernard Moss et al.	
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_	Other D	ocuments (include Author, Title, Date, and Place of Publication)
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Initial	Desig. ID	Document
	ADDDD	Esparza and Bhamarapravati, "Accelerating the development and future availability of JIV-1 vaccines: why, when, where, and how?", Lancet, 355: 2061-6, 2000.
	AEEEE	Evans DT et al., "Virus-specific T-lymphocyte responses select for amino-acid variation in simian immunodeficiency virus Env and Nef," Nat. Med., 5: 1270-1276, 1999.
	AFFFF	Feltquate et al., "Different T Helper Cell Types and Antibody Isotypes Generated by Saline and Gene Gun DNA Immunization," J. Immunol. 158: 2278-2284, 1997.
	AGGGG	Feinberg et al., "AIDS vaccine models" Challenging challenge viruses" Nature Med. 8(3):207-210, 2002.
	АНННН	Finzi et al., "Latent infection of CD4 T cells provides a mechanism for lifelong persistence of HIV-1, even in patients on effective combination therapy", Nat. Med. 5: 1270-6, 1996.
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	AJJJJ	Fu et al., "Priming of Cytotoxic T Lymphocytes by DNA Vaccines: Requirement for Professional Antigen Presenting Cells and Evidence for Antigen Transfer from Myocytes," Mol. Med., 3: 362-371, 1997.
	AKKKK	Furci et al., "Antigen-driven C-C Chemokine-mediated HIV-1 Suppression by CD4 T Cells from Exposed Uninfected Individuals Expressing the Wild-type CCR-5 Allele", J. Exp. Med., 186:455-60, 1997.
	ALLLL	Fynan et al., "DNA vaccines: Protective immunizations by parenteral, mucosal, and gene-gun inoculations," Proc. Natl. Acad. Sci. USA, 90: 11478-11482, 1993.
	AMMMM	Hakim et al., "A Nine-Amino Acid Peptide from IL-1β Augments Antitumor Immune Responses Induced by Protein and DNA Vaccines," J. Immunol., 157: 5503-5511, 1996.
	ANNNN	Hanke et al., "DNA multi-CTL epitope vaccines for HIV and Plasmodium faciparum: immunogenicity in mice," Vaccine, 16: 426-435, 1998b.
	A0000	Hartikka et al., "An Improved Plasmid DNA Expression Vector for Direct Injection into Skeletal Muscle," Hum. Gen. Therapy, 7: 1205-1217, 1996.
	APPPP	Hirsch et al., "Prolonged Clinical Latency and Survival of Macaques Given a Whole Inactivated Simian Immunodeficiency Virus Vaccine", J. Infect. Dis., 170:51-9, 1994.
	AQQQQ	Huang et al., "Human Immunodeficiency Virus Type 1-Specific Immunity" J. of Virology 75:4947-4951, 2001.
	ARRRR	Inchauspe et al., "Plasmid DNA Expressing a Secreted or a Nonsecreted Form of Hepatitis C Virus Nucleocapsid: Comparative Studies of Antibody and T-Helper Responses Following Genetic Immunization," DNA Cell Biol., 16: 185-195, 1997.
	ASSSS	Iwasaki et al., "Enhanced CTL responses mediated by plasmid DNA immunogens encoding costimulatory molecules and cytokines," J. Immunol., 158: 4591-4601, 1997a.
	ATTTT	Iwasaki et al., "The dominant role of bone-marrow derived cells in CTL induction following plasmid DNA immunization at different sites," J. Immunol., 159: 11-14, 1997b.
	AUUUU	Jacobsen et al., "Characterization of Human Immunodeficiency Virus Type 1 Mutants with Decreased Sensitivity to Proteinase Inhibitor Ro 31-8959," J. Virology 206:527-537 (1995).
	AVVVV	Jin et al., "Dramatic Rise in Plasma Viremia after CD8 T Cell Depletion in Simian Immunodeficiency Virus-infected Macaques", J. Exp. Med., 189: 991-8, 1999.

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ner Initial	Desig. ID	Document
	AWWWW	Jones et al., "Poly (DL-lactide-co-glycolide)-encapsulated plasmid DNA elicits systemic and mucosal antibody responses to encoded protein after oral administration," Vaccine, 15: 814-817, 1997.
	AXXXX	Kawabata et al., "The Fate of Plasmid DNA After Intravenous Injection in Mice: Involvement of Scavenger Receptors in Its Hepatic Uptake," Pharm. Res., 12: 825-830, 1995.
	AYYYY	Kent et al., "Enhanced T-Cell Immunogenicity and Protective Efficacy of a Human Immunodeficiency Virus Type 1 Vaccine Regimen Consisting of Consecutive Priming with DNA and Recombinant Fowlpox Virus," J. Virol., 72: 10180-10188, 1998.
14 14	AZZZZ	Kern et al., "Target structures of the CD8(+)-T-cell response to human cytomegalovirus: the 72-kilodalton major immediate-early protein revisited," J. Virol., 73: 8179-8184, 1999.
	AAAAA	Knapp et al., "A high frequency of Mamu-A*01 in the rhesus macaque detected by polymerase chain reaction with sequence-specific primers and direct sequencing," Tissue Antigens, 50: 657-661, 1997.
	ABBBBB	Kong et al., "Immunogenicity of Mutliple Gene and Clade Human Immunodeficiency" J. of Virology 77(23):12764-12772, 2003.
	ACCCCC	Korber et al., "Epidemiological and Immunological Implications of the Global Variability of HIV"  Retroviral Immunology, B. Walker, D. Pantaleo, Eds (The Humana Press, Totowa, NH, In press)
	ADDDDD	Kuroda et al., "Analysis of Gag-specific Cytotoxic T Lymphocytes in Simian Immunodeficiency Virus-infected Rhesus Monkeys by Cell Staining with a Tetrameric Major Histocompatibility Complex Class I-Peptide Complex," J. Exp. Med., 187: 1373-1381, 1998.
	AEEEEE	Lau et al., "Cytotoxic T-cell memory without antigen", Nature, 369: 648-52, 1994.
	AFFFFF	Letvin <i>et al.</i> , "Cytotoxic T lymphocytes specific for the simian immunodeficiency virus", Immunol. Rev., 170: 127-34, 1999.
	AGGGGG	Letvin, N.L. "Progress in the development of an HIV-1 vaccine" Science 280:1875-1880, 1998.
	АННННН	Letvin et al., "Potent, protective anti-HIV immune responses generated by bimodal HIV envelope DNA plus protein vaccination," Proc. Natl. Acad. Sci. USA, 94: 9378-9383, 1997.
	AIIIII	Levy et al., "Controlling HIV pathogenesis: the role of the noncytotoxic anti-HIV response of CD8 T cells", Immunol. Today, 17: 217-24, 1996.
	AJJJJJ	Lew et al., "Cancer Gene Therapy Using Plasmid DNA: Pharmacokinetic Study of DNA Following Injection in Mice," Hum. Gene Ther., 6: 553, 1995.
	AKKKKK	Lewis, et al., "Limited Protection from a Pathogenic Chimeric Simian-Human Immunodeficiency Virus Challenge following Immunization with Attenuated Simian Immunodeficiency Virus", J. Virol., 73: 1262-70, 1999.
	ALLLLL	Li et al., "Infection of Cynomolgus Monkeys with a Chimeric HIV-2/SIV <sub>mac</sub> Virus That Expresses the HIV-1 Envelope Glycoproteins," J. of AIDS, 5: 639-646, 1992.
	AMMMMM	Lifson et al., "The Extent of Early Viral Replication Is a Critical Determinant of the Natural History of Simian Immunodeficiency Virus Infection", J. Virol., 71: 9508-14, 1997.
	ANNNNN	Livingston et al., "The Induction of Mucosal Immunity in the Female Genital Tract Using Gene-Gun Technology (Part 1: Antigen Expression)," Ann. New York Acad. Sci., 772: 265-267, 1995.
	A00000	Lu et al., "SIV DNA vaccine trial in macaques: post-challenge necropsy in vaccine and control groups," Vaccine 15: 920-923, 1997.

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	AQQQQ	Maecker et al., "Cytotoxic T Cell Responses to DNA Vaccination: Dependence on Antigen Presentation via Class II MHC <sup>1</sup> ," J. Immunol., 161: 6532-6536, 1998.
	ARRRRR	Mahnel et al., "[Experiences with immunization against orthopox viruses of humans and animals using vaccine strain MVA]," Berl. Munch Tierarztl Wochenschr, 107: 253-256, 1994. [ENGLISH TRANSLATION OF ABSTRACT ATTACHED]
	ASSSS	Manthorpe et al., "Gene Therapy by Intramuscular Injection of Plasmid DNA: Studies on Firefly Luciferase Gene Expression in Mice," Hum. Gene Therapy, 4: 419-431, 1993.
	ATTTTT	Markmeyer et al., The pAX plasmids: new gene-fusion vectors for sequencing, mutagenesis and expression of proteins in E.coli," Gene 93:129-134 (1990).
	AUUUUU	Mayr et al., "[The smallpox vaccination strain MVA: marker, genetic structure, experience gained with the parenteral vaccination and behavior in organisms with a debilitated defence mechanism (author's transl)]," Zentralbl. Bakteriol., 167: 375-390, 1978. [ENGLISH TRANSLATION OF ABSTRACT ATTACHED]
	AVVVVV	McCluskie et al., "Direct Gene Transfer to the Respiratory Tract of Mice with Pure Plasmid and Lipid-Formulated DNA", Antisense Nucleic Acid Drug Dev., 8: 401-414, 1998.
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	AXXXXX	Meyer et al., "Mapping of deletions in the genome of highly attenuated vaccinia virus MVA and their influence on virulence," J. Gen. Virology 72:1031-1038 (1991).
	AYYYYY	Mizuno et al., "Mutational analysis of two zinc-finger motifs in HIV type 1 nucleocapsid proteins: effects on proteolytic processing of Gag precursors and particle formation, "Aides Research and Human Retroviruses 12(9): 793-800 (1996).
	AZZZZZ	Montgomery et al., "Heterologous and Homologous Protection Against Influenza A by DNA Vaccination: Optimization of DNA Vectors," DNA Cell Biol., 12: 777-783, 1993.
	AAAAAA	Moore et al., "HIV-1 neutralization: the consequences of viral adaptation to growth on transformed T cells," AIDS, 9(Suppl. A):S117-136, 1995.
	АВВВВВВ	Murali-Krishna et al., "Counting Antigen-Specific CD8 T Cells: A Reevaluation of Bystander Activation during Viral Infection," Immunity, 8:177-187, 1998.
	ACCCCCC	Murali-Krishna et al., "Persistence of Memory CD8T Cells in MHC Class 1-Deficient Mice", Science, 286:1377-81, 1999.
	DDDDDD	Pal et al., "Inhibition of HIV-1 Infection by the β-Chemokine MDC", Science, 278: 695-8, 1997.
	AEEEEEE	Persson et al., "Modifications of HIV-1 Retrovirus-Like Particles to Enhance" Biologicals 26:255-265, 1998.
	AFFFFF	Pertmer and Robinson, "Studies on Antibody Responses Following Neonatal Immunization with Influenza Hemagglutinin DNA or Protein," Virology, 257:406-414, (1999).
	AGGGGGG	Pertmer et al., "Influenza Virus Nucleoprotein-Specific Immunoglobin G Subclass and Cytokine Responses Elicited by DNA Vaccination Are Dependent on the Route of Vector DNA Delivery," J. Virol., 70: 6119-6125, 1996.

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	AIIIII	Poignard et al., "Neutralizing Antibodies Have Limited Effects on the Control of Established HIV-1 Infection In Vivo," Immunity, 10: 431-438, 1999.
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 12804-027001	Application No. 10/646,628
Information Disclosure Statement by Applicant (Use several sheets if necessary)  (37 CFR §1.98(b))		Applicant Bernard Moss et al.	
		Filing Date August 22, 2003	Group Art Unit 1645

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Initial	Desig. ID	Document	
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